UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,454	02/08/2005	Monique Berwaer	2004_0980A	2307

513 7590 05/16/2008

WENDEROTH, LIND & PONACK, L.L.P.
2033 K STREET N. W.
SUITE 800
WASHINGTON, DC 20006-1021

EXAMINER	
SILVERMAN, ERIC E	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
05/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/500,454	BERWAER ET AL.	
	Examiner	Art Unit	
	Eric E. Silverman, PhD	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' reply, filed 2/22/2008 has been received. Claims 3, 6, and 8 – 22 are pending, claims 11 – 22 being newly added.

Response to Amendment

The declaration under 37 CFR 1.132 filed 2/23/2007 is insufficient to overcome the rejection of claims 3, 6, and 8 – 10 based upon Rotini, the '815 reference, Kreutner, and Guy (and Addicks for claim 10) as set forth in the last Office action because: the showing in the declaration is not commensurate in scope with the instant claims. The showing in the declaration is limited to one specific dosage form having one specific set of ingredients in specific amounts. The instant claims, except for claim 10, do not specify any specific active ingredient. Claim 10 specifies certain specific excipients, but there is nothing in the declaration that supports the notion that it is these specific excipients, present in any amount (the claim does not specify the amount) that gives rise to the unexpected properties, namely, that the unexpected absence of a decrease in Cmax after eating (as compared to Cmax when fasting).

For the same reasons, this declaration is not effective for newly added claims 11, 12, and 14 – 22. The declaration is effective for claim 13 which is limited to (by a combination of its own limitations and those of the intervening and independent claims) the dosage form of the declaration.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 6, and 8 – 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites, in pertinent part, "having bioequivalence to two administrations of 5 – 25 mg of efletirizine in an immediate release form given 12 hours apart." Claim 11 has a similar recitation, but requires bioequivalence to two administrations of 15 mg immediate release efletirizine given 12 hours apart.

These claims are indefinite because they compare the claimed composition with some hypothetical immediate release composition, but never define the immediate release composition's characteristics. As such, the recited hypothetical immediate release system is not a sufficient basis for comparison. As an illustration, the bioactivity of an immediate release system will depend, upon the nature of the binder, disintegrant, compression matrix (if any), and other ingredients. An immediate release system, if orally delivered, may be configured to release the agent in the mouth under the influence of saliva, in the stomach, or in some other part of a gastroinstinal tract. But an immediate release system need not be orally administered; parenteral or inter venous administration may also be immediate release (for example, from micelles, liposomes, nanoparticles, or related vesicles). An intra venous system would clearly have a different bioactivity from any oral system, though both may be "immediate release".

Without knowing exactly what sort of immediate release system the instantly claimed system is being compared to, it is impossible to determine what limitations on the bioactivity are included in the instant claims.

The remaining claims are rejected at least for ultimately depending on claim 1 or 11 without clarifying the issue, thereby incorporating the indefinite limitations of claim 1 or 11.

Claims 15 – 22 refer to the "excipient of matricial type" being present in a specified concentration range. According to claim 1, the excipient of matricial type is present in the prolonged-release fraction, but need not be present in the immediate release fraction. It is not clear if the concentrations recited in the instant claims are relative to the weight of the total composition, or if they are relative only to the weight of the prolonged release fraction.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3, 6, 8, 9, 11, 14 - 18, and 20 – 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over us 5,043,167 TO Rotini in view of DERWENT-ACC-NO 1999-585815 (the '815 reference), US 5,869,479 to Kretner and US 3,906,086 to Guy for reasons of record and those discussed below.

1. The new claims' limitations

Rotini teaches the use of ethylcellulose in example 2. Ethylcellulose is an inert matrix of claim 14, a thermoplastic polymer of claims 15 and 16, and a hydrophilic

matrix (cellulose derivative) of claims 17 and 18. At col. 3, Rotini also suggests the inclusion of magnesium stearate or stearic acid, a lipid matrix of claim 20, a fatty acid of claim 21, and (for stearic acid) a material listed in claim 22. Ethylcellulose is used as a retarding agent, which may be in amounts of 40% to 60% (claim 2). The amount of stearate is not specified, but determining the working or optimal amount of a material in a composition is not a basis for non-obviousness when the general conditions of the invention have been set forth in the prior art.

2. Response to Applicants' arguments

Applicants' arguments have been fully considered, but they are not persuasive. Applicants argue that amended claim 1 is now commensurate with the scope of the declaration, and thus should be allowable. In response, the declaration is insufficient with respect to claim 1 for reasons discussed above. Applicants argue that the remaining claims are allowable by virtue of their depending con claim 1. As claim 1 is not allowable, this argument is not persuasive.

Claim 10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over ,043,167 TO Rotini in view of DERWENT-ACC-NO 1999-585815 (the '815 reference), US 5,869,479 to Kretner and US 3,906,086 to Guy and in further view of US 6,274,168 to Addicks et al for reasons of record and those discussed below.

1. The new claims' limitations

Claim 12 differs from claim 1 in that it requires a specific amount of HPMC. Determining the optimal or workable amount of a material does not overcome a holding of obviousness when the general conditions are known in the art. Here, the use of

HPMC is known in Addicks, and so determining the ideal amount is not a basis for patentability.

2. Response to Applicants' arguments.

Applicants' arguments have been fully considered, but they are not persuasive. Applicants argue that this claim is allowable for essentially the same reasons that claim 1 is alleged to be allowable. This argument is not persuasive for the same reasons that the argument with respect to claim 1 is not persuasive.

Claims 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over us 5,043,167 TO Rotini in view of DERWENT-ACC-NO 1999-585815 (the '815 reference), US 5,869,479 to Kretner and US 3,906,086 to Guy, as applied to claims 3, 6, 8, 9, 11, 14 - 18, and 20 – 22 and in further view of US 4,966,768.

What is lacking from Rotini, '815 reference, Kretner and Guy is one of the matrix agents of instant claims, such as HPMC.

The '768 reference teaches the use of ethylcellulose in combination with hydroxypropylcellulose (HPMC) in a prolonged release dosage form in an amount of 15 – 28 weight percent. Claim 1.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to add HPMC to the dosage form of the other references. Note that Rotini teaches the use of ethylcellulose in a prolonged release section. Obviousness stems from the fact that the instant claim is no more than use of a known prolonged release excipient to achieve prolonged release of an active. Use of a material for its art recognized useful purpose is generally obvious.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is (571)272-5549. The examiner can normally be reached on Monday to Thursday 7:00 am to 5:00 pm and Friday 7:00 am to noon.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571 272 0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Eric E. Silverman, PhD
Art Unit 1618